

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances. However, if a pharmacy employs a computer application for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

§ 1304.05 Records of authorized central fill pharmacies and retail pharmacies.

(a) Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central

fill pharmacies, including name, address and DEA number, that are authorized to fill prescriptions on its behalf. The retail pharmacy must also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf. These records must be made available upon request for inspection by DEA.

(b) Every central fill pharmacy must keep a record of all retail pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy must also verify the registration for all retail pharmacies for which it is authorized to fill prescriptions. These records must be made available upon request for inspection by DEA.

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§ 1304.06 Records and reports for electronic prescriptions.

(a) As required by § 1311.120 of this chapter, a practitioner who issues electronic prescriptions for controlled substances must use an electronic prescription application that retains the following information:

(1) The digitally signed record of the information specified in part 1306 of this chapter.

(2) The internal audit trail and any auditable event identified by the internal audit as required by § 1311.150 of this chapter.

(b) An institutional practitioner must retain a record of identity proofing and issuance of the two-factor authentication credential, where applicable, as required by § 1311.110 of this chapter.

(c) As required by § 1311.205 of this chapter, a pharmacy that processes electronic prescriptions for controlled substances must use an application that retains the following:

(1) All of the information required under § 1304.22(c) and part 1306 of this chapter.

(2) The digitally signed record of the prescription as received as required by § 1311.210 of this chapter.

(3) The internal audit trail and any auditable event identified by the internal audit as required by § 1311.215 of this chapter.

(d) A registrant and application service provider must retain a copy of any